K083067

FEB - 2 2009

OSSTEM Implant Co., Ltd.
#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804 Republic of Korea
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: September 30, 2008

1. Company and Correspondent making the submission:

- Submitter's Name :	OSSTEM Implant Co., Ltd.
- Address :	#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804, Republic of Korea
- Contact :	Mr. JongHyuk Seo

2. Device :

Trade or (Proprietary) Name :	MS System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE

3. Predicate Device :
MS System (Denture), OSSTEM Implant Co., Ltd. (K072959)
MS System (Narrow Ridge), OSSTEM Implant Co., Ltd. (K080594)

4. Description :
The MS System is a dental implant made of Ti-6Al-4V metal.
The MS System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface treatment of MS System is R.B.M (Resorbable Blasting Media).

The MS System is substantially equivalent in design, function and intended use to the MS System (Denture) and MS System (Narrow Ridge) of OSSTEM Implant Co., Ltd, (K072959, K080594)

5. Indication for use :
The MS System (Denture) is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. MS System (Denture) is intended for single use only.

The MS System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS System (Narrow Ridge) is intended for single use only. It is not for immediate load.

6. Review :
The MS System has similar material, indication for use, design and technological characteristics as the predicate device.

The MS System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Conclusion :
Based on the information provided in this premarket notification Osstem concludes that the MS System is safe and effective and substantially equivalent to the predicate device as described herein

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■ Predicate Devices

	MS System (Narrow Ridge)	MS System (Denture)	Secure Implant System
510K	**K080594**	**K072959**	**K080129**
Design			
Intended Use	The MS System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS System (Narrow Ridge) is intended for single use only. It is not for immediate load.	The MS System (Denture) is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. MS System (Denture) is intended for single use only.	Secure Implant System (2.5/3.0mm) is designed for use in dental implant surgery and is intended for use in a manner in which the implants integrate with the bone (osseointegration). It is intended to provide immediate transitional splinting stability or intrabony long-term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients.
Body Diameter (D)	3.0	2.0~3.0	2.5, 3.0
Length (mm)	10.0, 13.0, 15.0	10.0, 13.0, 15.0	10.0, 12.0, 14.0, 16.0
Surface	RBM	RBM	RBM
Material	Titanium alloy Ti-6Al-4V (ASTM F 136-02A)	Titanium alloy Ti-6Al-4V (ASTM F 136-02A)	Titanium alloy Ti-6Al-4V (ASTM F 136-02A)
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Osstem Implant Company, Limited
C/O Mr. MinJoo Kim
Manager
Hiossen, Incorporated
85 Ben Fairless Drive
Fairless, Pennsylvania 19030

Re: K083067
Trade/Device Name: MS System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental implant
Regulatory Class: II
Product Code: DZE
Dated: January 7, 2009
Received: January 12, 2009

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K _____

Device Name: MS System

Indication for use : The MS System (Denture) is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. MS System (Denture) is intended for single use only.

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Prescription Use___X____ (Per 21CFR801 Subpart D)

OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K053067